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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,505	02/18/2004	Rafail Zubok	532-3X6	2913
530 7590 07/21/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER CUMBERLEDGE, JERRY L				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,505

Applicant(s)

ZUBOK ET AL.

Examiner

JERRY CUMBERLEDGE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 12, 13 and 15-18 is/are rejected.
- 7) ☒ Claim(s) 5 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 10, 12, 13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham (US Pat. 5,246,458).

Graham discloses a drill assembly, comprising: an intervertebral disc replacement device (Fig. 1, ref. 14) including first (Fig. 1, ref. 16) and second members (Fig. 1, ref. 28) for insertion into an intervertebral disc space of a spinal column, the first member including a first articulation surface (Fig. 2, near ref. 38) and a first flange (Fig. 2, ref. 16) having at least one first through hole (Fig. 4, ref. 44a) and the second member including a second articulation surface (Fig. 2, ref. 36) and a second flange (Fig. 2, ref. 26) having at least one second through hole (Fig. 1, ref. 44c), the first and second articulation surfaces allowing for movement of the first member with respect to the second member (Fig. 2); an insertion plate (Fig. 1, ref. 42) removably connected with the first and second members (Fig. 3, Fig. 4) for maintaining the first and second articulation surfaces of the first and second members in registration with one another (Fig. 1), the insertion plate including a first alignment element (Fig. 1, e.g. ref. 76a, holes through plate); and a drill guide (Fig. 5, ref. 56) removably connected with at least the insertion plate, the drill guide including: a shaft (Fig. 5, ref. 52) having a proximal end

and a distal end (Fig. 5); and a guide member (Fig. 5) disposed at the distal end of the shaft (Fig. 5) and operable to engage the insertion plate (Fig. 5), wherein the guide member includes at least one guide bore (Fig. 5, bore through ref. 48) aligned with one of the first or second through holes and an area of a vertebral bone of the intervertebral disc space to which one of the first and second members of the intervertebral disc replacement device is to be attached (Fig. 4) and a second alignment (Fig. 5, ref. 48) element engaged with the first alignment element of the insertion plate (Fig. 5). The first alignment element and the second alignment element enable a target orientation of a longitudinal axis of the guide bore relative to at least one of the vertebral bone and one of the first and second members of the intervertebral disc replacement device (Fig. 5). One of the first alignment element and the second alignment element includes an alignment stem and the other of the first alignment element and the second alignment element includes an alignment bore (Fig. 5), the alignment stem being receivable within the alignment bore (Fig. 5) to enable the target orientation of the longitudinal axis of the guide bore (Fig. 5). The guide member includes a posteriorly directed surface (Fig. 5, end of ref. 48) and a spaced apart anterior directed surface (Fig. 5, opposite end of ref. 48); the second alignment element of the guide member includes the alignment bore extending from the posteriorly directed surface at least partially through the guide member toward the anteriorly directed surface (Fig. 5); and the second alignment element of the insertion plate includes the alignment stem extending in an anterior direction for engagement with the alignment bore (Fig. 5). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 1,

near. ref. 18) and the first through hole is capable of receiving a bone screw for fastening the first member to the vertebral bone of the spinal column (Fig. 1); and the guide member of the drill guide further includes a third alignment element (Fig. 5, end of ref. 52) operable to engage the first through hole of the first flange when the alignment stem is received within the alignment bore to further enable the target orientation of the longitudinal axis of the guide bore (Fig. 5). The alignment bore has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig. 5). The guide member is operable to achieve at least first and second alignment modes with respect to the insertion plate, in the first alignment mode, the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with the first through hole of the first member and an area of a first vertebral bone of the intervertebral disc space to which the first member of the intervertebral disc replacement device is to be attached (Fig. 5), and in the second alignment mode, the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with the second through hole of the second member and an area of a second vertebral bone of the intervertebral disc space to which the second member of the intervertebral disc replacement device is to be attached (Fig. 5). One of the first alignment element and the second alignment element includes an alignment stem and the other of the first alignment element and the second alignment element includes an alignment bore (Fig. 5), the alignment stem being receivable within the alignment bore to enable rotational adjustment of the guide member relative to the insertion plate and to achieve the first and second alignment modes (Fig. 5). The guide member of the drill guide further includes at least a third

alignment (Fig. 5, end of ref. 52) element operable to: (i) engage the first through hole of the first flange when the alignment stem is received within the alignment bore in the first alignment mode to further enable a first target orientation of the longitudinal axis of the guide bore (Fig. 5), and (ii) engage the second through hole of the second flange when the alignment stem is received within the alignment bore in the second alignment mode to further enable a second target orientation of the longitudinal axis of the guide bore (Fig. 5). The alignment bore has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig. 5). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 5, near ref. 18) and at least two first through holes (Fig. 5, refs. 44, 44a) for receiving respective bone screws for fastening the first member to the first vertebral bone of the spinal column (Fig. 5); the second member of the intervertebral disc replacement device includes a second vertebral contact surface (Fig. 5, near ref. 28) and at least two second through holes (Fig. 5, ref. 44b and other hole) for receiving respective bone screws for fastening the second member to the second vertebral bone of the spinal column.

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Graham which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA

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1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US Pat. 5,246,458).

Graham discloses the claimed invention except for the fourth alignment element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the device of Graham with a fourth alignment element, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments with respect to claims 1-10 and 12-18 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 5 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JERRY CUMBERLEDGE** whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733